UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,741	10/06/2003	Dehchuan Sun	U 014844-2	2807

7590 07/11/2005

EXAMINER
NASSER, ROBERT L

ART UNIT	PAPER NUMBER
3736	

Ladas & Parry
26 West 61st Street
New York, NY 10023

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,741	SUN, DEHCHUAN	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1 121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/20/04 & 6/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims is rejected as being indefinite in that no method claims are recited. Specifically, method claims must be in the active voice. Applicant should amend the claims to recite utilizing the device of claim ____ to . . . . In addition, claim 8 is rejected in that it is unclear what the vibrations are that the claim refers to.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 7, 9, 12, 14, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodman 6616613. Goodman has a pulse wave sensor, i.e. PPG sensor 12, which senses the pulse wave and transmits the signal to an analyzer 6 which analyzes the signal to determine parameters including the trough point (see figure 14). The analyzer 5 further has a display. With respect to claims 6 and 7, Goodman's computer 5 has a connection via the Internet to a terminal for a doctor and receive signals back therefrom., either through a wire or wirelessly. Claims 9, 12, 14,and 15 are rejected in that Goodman the apparatus of these claims to measure the pulse wave.

With respect to the apparatus claims, Goodman does not evaluate drug hepatoxicity. However, the claim does not require a determination of whether a drug is toxic to the liver. If applicant were to recite a processor that received signals pre and post drug delivery and used the signals to provide an output of drug toxicity, it would overcome this rejection.

With respect to the method claims, again, there is no positive step of determining hepatoxicity of a drug. If applicant were to rewrite the claim to affirmatively state that the system indicates liver function side effect when certain conditions were met, it would overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Amano 2003/0125631. Goodman uses a wrist mounted PPG pulse wave sensor. In paragraph 64, Amano teaches the equivalence of pressure sensors and optical sensors for measuring the pulse wave. Hence, it would have been obvious to modify Goodman to use a pressure sensor, as it is merely the substitution of one known equivalent sensor for another.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Niwa 5140991. Niwa further teaches that it is well known to

provide an alarm when the pulse wave is abnormal. From this teaching, it would have been obvious to modify Goodman to use an alarm, to inform the user and allow for immediate attention.

Claims 8 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Mori 2004/0059202 in view of Amano 2003/0125631 and Goodman. Mori shows a device that has a pulse wave sensor 102 which sense a pulse wave, which senses a pulse wave signal which can be analyzed for waveform parameters, sends the signal to a processing monitor (bedside monitor) 121,which takes the fft of the signal and processes the signal, which includes analyzing the angle of the frequency signal. In addition, the device communicates bidirectionally via the Internet with a physician location which has a server and a terminal machine. It does not specify whether the sensor is a wrist sensor. However, Amano further teaches measuring the pulse wave from the wrist. Hence, it would have been obvious to modify Mori to use a wrist sensor, as it is merely the substitution of one known equivalent sensor for another. In addition, the amplifier/converter/buffer etc are not in the monitor but in the sensor. However, Goodman shows an alternate device where the signal processing hardware in the monitor. As such, it would have been obvious to modify the above combination to locate the processing hardware in the monitor, as it is merely the substitution of one known equivalent arrangement for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Amano 2004/0267141 and Kanda EP 0359206 determine liver function from a pulse wave.

Dai et al evaluates hepatoxicity using tissue chemicals (see pages 11 and 12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
July 6, 2005

ROBERT L. NASSER
PRIMARY EXAMINER